K132618

DEC 16 2013

4. 510(k) Summary

Name of Firm:	LifeScan Inc. A Johnson & Johnson Company 965 Chesterbrook Bld. Wayne, PA 19087
Primary 510(k) Contact:	Gabrielle Logan Regulatory Affairs Analyst LifeScan Inc. A Johnson & Johnson Diabetes Care Franchise Phone: 484-328-6159 Fax: 610-651-7271 Email: GLogan2@its.jnj.com
Secondary 510(k) Contact:	Amy Smith Director, Regulatory Affairs Advanced Sterilization Products A Johnson & Johnson Company Phone: 949-789-3803 Email: ASmith21@its.jnj.com
Date Prepared:	August 19, 2013
Device Trade Name:	OneTouch® Reveal™
Device Generic Name:	Accessories, Pump, Infusion System Test, Blood Glucose, Over The Counter
Device Class:	II
Review Panel:	General Hospital
Product Code:	Classification Product Code: MRZ Subsequent Product Code: NBW
Regulation Number:	Infusion Pump 21 CFR § 880.5725
Predicate Device:	K101806 – Aidera Diasend System (Aidera AB)
Device Description:	OneTouch® Reveal™ is a Web-based Diabetes management system. The application is designed to assist health care professionals and people with diabetes to track blood glucose levels and insulin doses. The application identifies patterns to help patients manage glycemic control. OneTouch® Reveal™ includes pattern recognition messages, reports, and the ability to view patient data remotely.

Intended Use / Indications for Use:	OneTouch® Reveal™ is indicated for use by individuals or health care professionals in the home or health care facilities for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database to support diabetes management. The device is indicated for professional use and over-the-counter sales.
Comparison of the technological characteristics of the device to the predicate device:	The LifeScan Inc.'s OneTouch® Reveal™ is substantially equivalent to the legally marketed predicate, Aidera Diasend System and incorporates the following similar technology and functionality including: • OTC and Rx • Web-based software application • Manage patient accounts, filter/sort/search patients, print reports Unlike the predicate, the LifeScan Inc.'s OneTouch® Reveal™ does not use a transmitter to transfer data.
Performance Data (Nonclinical and/or Clinical):	Performance testing consisted of software verification and validation testing and Human Factors Usability Studies that demonstrated OneTouch® Reveal™ meets its required specifications and performs as intended.
Substantial Equivalence to Predicate Device:	Based on the information presented in this submission, OneTouch® Reveal™ does not raise new questions of safety and effectiveness and is substantially equivalent in its intended use, performance, safety, effectiveness and underlying scientific and operating principles compared to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 16, 2013

LifeScan Incorporated
A Johnson & Johnson Company
Ms. Gabrielle Logan
Regulatory Affairs Analyst
965 Chesterbrook Bld
Wayne, PA 19087

Re: K132618
Trade/Device Name: OneTouch® Reveal™
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ, NBW
Dated: November 13, 2013
Received: November 14, 2013

Dear Ms. Logan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer
-S for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132618

Device Name
OneTouch® Reveal™

Indications for Use *(Describe)*
OneTouch® Reveal™ is indicated for use by individuals or health care professionals in the home or health care facilities for transmitting data from home monitoring devices such as glucose meters and insulin pumps to a server database to support diabetes management. The device is indicated for professional use and over-the-counter sales.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman
Date: 2013.12.16 12:15:19 -05'00'